REMARKS

The present document is submitted in response to the Office Action dated January 24, 2011 ("Office Action").

Claims 1-12, 16, 17, 19-26, 28, 30, 31, 38-53, 67-69, 75, and 76 were previously pending in this application. Among them, claims 10, 19-23, 30, 31, 47, and 67-69 have been withdrawn from consideration.

By this amendment, Applicant has rewritten claim 5 in independent form and has amended this claim, as well as claim 3, to incorporate the features recited in previously presented claims 9 and 17, which are now cancelled. These amendments have necessitated revisions to claims 8, 11, and 12 and cancellation of claims16, 21-24, 40, 43, 46, and 47. Finally, Applicant has cancelled claims 1, 2, 19, 20, 28, 30, 31, 41, 44, 49, 51, and 69 and changed dependencies to claims 25, 26, 38, 39, 45, 48, 50, 75, and 76. The above-noted amendments have not introduced new matter.

Upon entry of the amendments summarized above, claims 3-8, 11, 12, 25, 26, 38, 39, 42, 45, 48, 50, 52, 53, 75, and 76 will be under examination. Applicant respectfully requests that the Examiner reconsider this application in view of the following remarks.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 1-9, 11-12, 16, 24-26, 38-40, 42-43, 45-46, 48-53 and 75-76 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Office Action, pages 3-4. More specifically, the Examiner alleges that these claims, directed to plant-produced antibodies, are not enabling as the claims fail to specify the antigen specificity of the claimed antibodies. As claims 1, 2, 9, 16, 24, 40, 43, 46, 49, and 51 have been cancelled, only claims 3-8, 11, 12, 25, 26, 38, 39, 42, 45, 48, 50, 52, 53, 75, and 76 remain at issue.

For the sole purpose of accelerating prosecution, Applicant has followed the Examiner's suggestion (Office Action, page 4, third paragraph) to incorporate in independent claims 3 and 5

the antigen specificity of the claimed plant-produced immunoglobulin, i.e., specific to herpes simplex virus, thereby obviating this rejection.

Rejections under 35 U.S.C. §103

The Examiner has rejected claims 1-9, 11-12, 16-17, 24-26, 28, 38-46, 48-53 and 75-76 under 35 U.S.C. §103(a) as being unpatentable over Elbers et al., Plant Physiology 126:1314-1322; 2001 ("Elbers") in view of Mayfield et al., US 2004/0014174 ("Mayfield"). Upon entry of the amendments noted above, only claims 3-8, 11, 12, 25, 26, 38, 39, 42, 45, 48, 50, 52, 53, 75, and 76 remain at issue. Applicant provides reasons below that these claims, as amended, are not obvious over Elbers in view of Mayfield.

The claims as amended are directed to anti-herpes simplex virus IgA antibodies produced in plants. As set forth in independent claims 3 and 5, the claimed IgA antibodies have a free glycan profile containing at least one glycan that is 2Man, 2GlcNAc, 1Xyl, in which Man refers to mannose, GlcNAc refers to N-acetylglucosamine, and Xyl refers to xylose. See also Figure 12 in the instant specification.

Elbers reports a mouse IgG antibody produced in plants. Abstract and page 1319, right column, third paragraph. This reference shows in Table II the types of N-glycans isolated from the IgG antibody produced in plants under different growth conditions. Page 1318. The 2Man, 2GlcNAc, 1Xyl glycan required by the claimed plant-produced IgA antibodies is not included in Table II. This indicates that the IgG antibody reported in Elbers differs from the claimed IgA antibodies in at least one aspect. That is, the former does not contain the 2Man, 2GlcNAc, 1Xyl glycan required by the latter.[1] In other words, Elbers does not teach or suggest a plant-produced IgA antibody having the glycan profile as required by the claims at issue.

Mayfield reports producing a single-chain IgA antibody in plant chloroplasts. Paragraph [0018]. According to this reference, polypeptides expressed in plant chloroplasts "are not subject to certain post-translational modifications such as glycosylation." Paragraph [0087]. Clearly, the IgA

[1] Figure 12 in the instant application shows a glycan profile of an exemplary IgA antibody produced in plant. Applicant would like to point out that this glycan profile, recited in claim 7, is very different from the glycan profile of the plant-produced IgG antibody reported in Elbers, Table II.

single-chain antibody reported in Mayfield is not glycosylated, i.e., containing no glycans, such as the 2Man, 2GlcNAc, 1Xyl glycan required by the claimed invention. Thus, Mayfield cannot cure the deficiency in Elbers.

For at least the reasons set forth above, the combination of Elbers and Mayfield does not render the claims at issue obvious.

To complete the record, Applicant addresses below the Examiner's ground in support of this rejection.

The Examiner states:

> Both Elbers and Mayfield expressed desire to alter glycopeptides profile in plant-produced antibodies for therapeutic use with regards to immunogenicity. Therefore, one or ordinary skill in the art would have been motivated to combine the teachings of both Elbers and Mayfield and produce an anti-HSV IgA antibody as taught by Mayfield with an altered glycopeptide profile as taught by Elbers. Office Action, page 7, first paragraph.

Applicant respectfully disagrees for the following reasons:

Elbers points out that "[t]he specific composition and structures of these sugar oligomers are crucial for the biological activity, stability, solubility, immunogenicity, and plasma clearance characteristics of many glycoproteins" and that "[r]elatively little is known about the effects of environmental and developmental conditions on the quality of recombinant proteins produced by plants grown in a controlled manner." Page 1315, first and last paragraphs. This reference aims at investigating "whether the adaptation of plant cells to some changes in environment and physiology is reflected in N-glycosylation." Page 1315, last paragraph. It reports the glycosylation patterns of endogenous proteins and an exogenous protein, i.e., a mouse IgG antibody, under different growth conditions. Table II. This reference is silent on the particular conditions for producing in plant glycosylated antibodies that have low immunogenicity.

By contrast, Mayfield teaches producing polypeptides (e.g., single-chain IgA) in chloroplasts of plant cells so as to obtain non-glycosylated polypeptides, which are expected to be low immunogenic. Paragraph [0087]. This is opposite to the teachings in Elbers, i.e., producing glycosylated antibodies under different growth conditions. Indeed, combining Elbers and Mayfield in the manner suggested by the Examiner, i.e., producing the anti-HSV IgA antibody taught by

Mayfield in plants following the teachings in Elbers, would result in a glycosylated IgA antibody, which would be in conflict with the goal of Mayfield, i.e., producing non-glycosylated IgA antibody so as to reduce immunogenicity. Thus, contrary to the statement in the Office Action quoted above, a skilled person in the art would have had no motivation to combine the teachings in these two cited references to arrive at the claimed invention. Moreover, the skilled artisan would have been discouraged from doing so in light of the teachings in Mayfield noted above.

In view of the above remarks, Applicant respectfully requests that the Examiner withdraw this rejection.

CONCLUSION

For the reasons set forth above, Applicant believes that the present application is in condition for allowance. Favorable consideration is therefore respectfully solicited.

No fee is believed to be due. If this reply is not considered timely filed and a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee due and authorization is not provided elsewhere for such fee, including an extension fee, please charge our Deposit Account No. 23/2825, under Docket No. P0850.70005US01.

Dated: March 23, 2011

Respectfully submitted,

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